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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,767	02/26/2001	David Edwin Thurston	65435-9002	6332

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/20/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,767

Applicant(s)

THURSTON et al.

Examiner

Brenda Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 18, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-10, 12, 13, 15-21, 25-29, 31-38, 40, 42-44, and 46-64 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, 12, 13, 15-21, 25-29, 31-38, 40, 42-44, and 46-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Claims 1, 3-10, 12, 13, 15-21, 25-29, 31-38, 40, 42-44 and 46-64 are pending in the application.

This action is in response to applicants' amendment filed February 18, 2003. Claims 1, 6, 13, 20, 29, 38, 40, 42-44 and 46-49 have been amended, claims 30, 41 and 45 have been canceled and claims 56-64 are newly added.

Response to Amendment

Applicants' arguments filed February 18, 2003 have been fully considered with the following effect:

1. The applicant's amendments are sufficient to overcome the objection to the Arrangement of the Specification, which is hereby **withdrawn**.
2. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claims 1, 3-10, 12, 13, 15-21, 25-35, 38, 40-44 and 46-55, labeled 3a) and 3b) maintained in the last office action, which are hereby **withdrawn**.
3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled 4d), 4e), 4n) and 4q) maintained in the last office action, which are hereby **withdrawn**.

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4. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 101, rejection labeled paragraph 5) maintained in the last office action, which is hereby **withdrawn**.

5. With regards to the obviousness-type double patenting rejection as being unpatentable over copending Application No. 09/763,813 in the last office action, the applicants stated that "the examiner has not established as a *prima facie* case of obviousness" and that "the examiner has provided no analysis as to the difference between the inventions claims by the conflicting claims compared to as a claim in the instant application, and so to the reasons why as a person of ordinary skill in the art would have concluded that the invention defined in the claims of the present invention is an obvious variant of the inventions defined in the claims of the copending applications". However, claims 17-19 of copending Application No. 09/763,813 embrace compounds, compositions and method of use of the compounds as claimed herein.

Claims 1, 3-7, 20, 21, 25-27, 29, 31-38, 40, 42-44, 46, 48-55 and newly added claims 56, 60, 61 and 63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-19 of copending Application No. 09/763,813. For reasons of record and stated above.

6. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claims 31 and 38, labeled 10a) and 10b) of the last office action, which are hereby **withdrawn**.

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7. With regards to the 35 USC § 112, first paragraph rejection of claims 38, 40, 41 and 43-49 in the last office action, the applicants' arguments have been fully considered but are not found persuasive. The applicants' stated that "the amendments to claims 38, 40, 43 and 44 and the cancellation of claims 41 and 45 obviate this rejection". However, there is no basis for the treatment of a cisplatin-refractory disease or the inhibition of the growth of cisplatin-refractory cells in the specification, nor is there any testing to indicate that the compounds of the instant invention are effective in the treatment of a cisplatin-refractory disease or the inhibition of the growth of cisplatin-refractory cells.

Claims 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For reasons of record and stated above.

8. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 38, 40, 41 and 43-49 in the last office action, the applicants' arguments have been fully considered, however they were not found persuasive. In the art of clinical oncology, no compound has yet shown clinical efficacy against every type of cancer. Different agents are used for different specific forms of cancer and no single agent is listed as a treatment of every single type of cancer. No compound has shown clinical efficacy against all cancers, thus no *in vivo* or *in vitro* assay could be validated for the identification of such a general agent. Applicants' specification logically must lack such assay data.

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Claims 43 and 44 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For the reasons of record and stated above.

9. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled 13a), 13b), 13c), 13d), 13e), 13f), 13g), 13h) and 13j) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled 13i) in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

- i) The applicants' stated that the "amendment to these claims obviate this rejection". However, claims 43 and 44 were not amended with respect to the use of the claimed compounds.

Claims 43 and 44 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

4. With regards to the 35 U.S.C. § 102 anticipation rejection of claims 50-55 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The instant claims are not described in the applicants priority document and thus are only entitled to benefit of PCT/GB99/02838 filed August 27, 1999 as it is only completely described in the

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international application of which the instant application is a national stage entry under 35 U.S.C. § 371. Note *In re Scheiber* 199 USPQ 782 regarding 112 compliance for benefit under 35 USC 120.

Claims 50-55 are rejected under 35 U.S.C. 102(a) as being anticipated by Gregson et al., Chem. Commun. For reasons of record and stated above.

10. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection labeled paragraph 15) of the last office action, which is hereby **withdrawn**.

In view of the amendment dated February 18, 2003, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is as a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain as a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1, 3-10, 12, 13, 15-21, 25-29, 31-33, 38, 40, 42, 44, 46-49 and 57-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following reasons apply:

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- a) The amendment to the definition of R_2 in claim 1 where R_2 is CH_2OR is not described in the specification. (Claims 1, 6-10, 12, 38, 42, 46, 60)
- b) The amendment to the definition of R_2 in claim 1 where R_2 is $CH=CR^A R^B$ is not described in the specification. (Claims 1, 3-5, 7-10, 38, 42, 46,
- c) The amendment to claims 1, 13, 20 and 29 where the definition of R includes “one or more carbonyl groups or one or more ether or thioether groups” is not described in the specification. (Claims 1, 3, 4, 7-10, 13, 15-21, 25-29, 31-33, 38, 40, 42, 46-49, 57-60)
- d) The amendment to claims 38 and 40 are such that the cancers lists includes cancers which are not described in the specification, such as melanoma, breast cancer, ovarian cancer, etc. (Claims 38, 40 and 60-64)
- e) The amendment to structural formula in claim 42 such that the five membered ring is optionally fully saturated is not described in the specification. (Claim 42)

Applicant is required to cancel the new matter in the reply to this Office action.

The following is as a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 21, 25-28, 31, 34, 43, 44, 50-56 and 60-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

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- a) Claim 21 recites the limitation "H" in the definition of R_8 . There is insufficient antecedent basis for this limitation in the claim. R_8 is NH_2 in the claim from which claim 21 depends.
- b) Claim 25 recites the limitation "aryl" in the definition of R_8 . There is insufficient antecedent basis for this limitation in the claim.
- c) Claim 25 recites the limitation "optionally contains one or more hetero atoms which may form part of, or be, a functional group" in the definition of R_6 , R_7 , R_8 and R_9 . There is insufficient antecedent basis for this limitation in the claim.
- d) Claim 26 recites the limitation "phenyl" in the definition of R_8 . There is insufficient antecedent basis for this limitation in the claim.
- e) Claim 26 recites the limitation "methoxy and ethoxy" in the definition of the substituents on the phenyl of R_6 , R_7 , R_8 and R_9 . There is insufficient antecedent basis for this limitation in the claim.
- f) Claim 27 recites the limitation "Ph" in the definition of R_8 . There is insufficient antecedent basis for this limitation in the claim.
- g) Claim 27 recites the limitation "p-MeO" in the definition of the substituents on the phenyl of R_6 , R_7 , R_8 and R_9 . There is insufficient antecedent basis for this limitation in the claim.

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- h) Claim 28 recites the limitation "the compound is a dimer, wherein the dimer bridge is of the formula $-O-(CH_2)_q-O-$, where q is from 3 to 12" in the definition of the compound. There is insufficient antecedent basis for this limitation in the claim.
- i) Claim 31 recites the limitation "electron donating group" in the definition of R_7 . There is insufficient antecedent basis for this limitation in the claim.
- j) Claim 34 is vague and indefinite in that it is dependent upon a canceled claim.
- k) Claims 43, 44 and 63 do not end with a period.
- l) Claims 50-55 are vague and indefinite in that it is not known what is meant by "optionally contains one or more hetero atoms which may form part of, or be, a functional group" in the definition of R.
- m) Claim 56 recites the limitation "4-methoxyphenyl" in the definition of R_2 . There is insufficient antecedent basis for this limitation in the claim.
- n) Claim 60 recites the limitation "4-methoxyphenyl" in the last species with respect to the definition of R_2 . There is insufficient antecedent basis for this limitation in the claim.
- o) Claim 61 recites the limitation "BnO" in the species with respect to the definition of R_8 . There is insufficient antecedent basis for this limitation in the claim.
- p) Claim 62 recites the limitation "cyclopentyl" in the species with respect to the five membered ring. There is insufficient antecedent basis for this limitation in the claim.

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- q) Claim 63 recites the limitation "FmocHN-CH₂-CH₂-CH₂-O" in the third species with respect to the definition of R₈. There is insufficient antecedent basis for this limitation in the claim.
- r) Claim 64 recites the limitation "CH₂-CH₂-CH₂-CH₂-CH₂-CH₂-CH₂" in the second species with respect to the definition of R₈. There is insufficient antecedent basis for this limitation in the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of as a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman
Primary Examiner AU 1624
May 18, 2003